NOV 01 2001

K011175

510(k) SUMMARY
W.O.M. Laser U100

I. Submitter / Manufacturing Facility, Contact Person:

Submitter / Manufacturing Facility:
W.O.M. WORLD OF MEDICINE AG
Alte Poststraße 11, 96337 Ludwigsstadt
Germany
Phone: 011 49 39981 560
Fax: 011 49 39981 593
susanne.raab@womcorp.com

Contact Person:
Micheal McGrail
Regulatory Consultant
194 Branch St.
Mansfield, MA 02048
Phone: 011 49 39981 550
Fax: 011 49 39981 550
mjmcgrail@aol.com

II. Names:

1. Classification Name: FDA has not specifically classified Frequency-Doubled Nd:YAG Lithotripter.

2. Proprietary Name: W.O.M. Laser U100.

III. Predicate Device:

- Candela MDL-2000 LaserTripter (K901723).
- Dornier Medilas H/2 Laser (K984591)

IV. Class of the Device:

- Similar devices have been classified Class II.

V. Intended Use and Indication for Use:

- The W.O.M. Laser U100 is intended for use in endoscopic surgical procedures to fragment stones.

- The W.O.M. Laser U100 is indicated for use to fragment urinary stones in the contact mode during closed surgical procedures.

VI. Technical Characteristics and Substantial Equivalence:

The W.O.M. Laser U100 has the same intended use, similar design features and similar principles of operation as the Candela MDL 2000 LaserTripter (K K901723). The W.O.M. Laser U100 has the same intended use as the Dornier Medilas H/2 Laser (K984591).

The W.O.M. Laser U100 and the predicate devices are indicated for use to fragment urinary stones during closed surgical procedures. The Dornier Medilas H/2 Laser (K984591), however, is a Ho:YAG laser and is also indicated for use in cutting, vaporization, ablation and coagulation of soft tissue. Accordingly, the Dornier Medilas H/2 Laser (K984591) presents an increased risk of tissue injury when used to fragment urinary stones during closed surgical procedures.

Although the W.O.M. Laser U100 and the Candela MDL 2000 LaserTripter (K901723) generate their respective laser beams through different physical processes, the characteristics of the treatment beams (wavelength, pulse energy, pulse duration and pulse frequency) are similar. Moreover, the method of transmission to the stone (laser fiber) is similar and both devices provide aiming beams to allow visual indication of the stone location.

Both devices incorporate an internal water cooling cycle with a water-air heat exchanger system. In addition, the devices provide similar safety features and similar parameters are displayed on the operator panel of the devices.

Both the W.O.M. Laser U100 and Candela MDL 2000 LaserTripter (K901723) transmit pulses of laser energy by a quartz fiber to the stone (contact mode). The laser pulses are transformed into an ultrasonic wave (acoustic impact waves) which mechanically crush the stone. Unlike Ho:YAG lasers, the laser effect of both devices is thus non-thermal and does not lead to a critical heating of the operating area. This represents a substantial improvement in the safety of laser lithotripsy by avoiding the risk of tissue injury that may result from the use of an Ho:YAG laser to fragment stones in the urinary tract.

VIII. Safety and Effectiveness Information:

Bench, in vivo and clinical data was provided to demonstrate that the W.O.M. Laser U100 is safe and effective for the fragmentation of urinary stones in closed surgical procedures.

IV. Conclusion:

The W.O.M. Laser U100 has the same intended use, similar design features and similar principles of operation as the Candela MDL 200 LaserTripter (K K901723). The W.O.M. Laser U100 has the same intended use as the Dornier Medilas H/2 Laser (K984591), however, the Dornier Medilas H/2 Laser (K984591) is a Ho:YAG laser that is also indicated for use in cutting, vaporization, ablation and coagulation of soft tissue. Accordingly, the W.O.M. Laser U100 allows for a significant reduction in the risk of tissue injury when used to fragment urinary stones during closed surgical procedures.

Bench, in vivo and clinical study results demonstrate that the W.O.M. Laser U100 is safe and effective for the fragmentation of urinary stones in closed surgical procedures. Therefore, the W.O.M. Laser U100 is substantially equivalent to the Candela MDL 200 LaserTripter (K K901723) and the Dornier Medilas H/2 Laser (K984591).

Signed: S Raab

Susanne Raab
Legal Department and Regulatory Affairs

April 2, 2001
Date:

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

W.O.M. World of Medicine, GmbH
c/o Mr. Michael McGrail
Regulatory Consultant
194 Branch Street
Mansfield, Massachusetts 02048

NOV 0 1 2001

Re: K011175
Trade/Device Name: W.O.M. Laser U100
Regulation Number: 878.4810 and 876.4480
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology, and Electrohydraulic Lithotriptor
Regulatory Class: II
Product Code: GEX, FFK
Dated: July 31, 2001
Received: August 3, 2001

Dear Mr. McGrail:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K011175

NOV 0 1 2001

STATEMENT OF INDICATIONS FOR USE

APPLICANT: W.O.M. WORLD OF MEDICINE AG

510(K) NUMBER: K011175

DEVICE NAME W.O.M. Laser U100

INDICATIONS FOR USE:

The W.O.M. Laser U100 is indicated for use in the contact mode to fragment urinary stones (kidney, ureter and bladder) in closed surgical procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 C.F.R. § 801.109)

(Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011175